

Application No. 10/672,689  
Amdt. dated June 7, 2006  
Reply to Office Action of Feb. 7, 2006

Amendment to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

**Listing of Claims:**

Claim 1 (Currently Amended) A method for preparing a native, acellular tissue replacement comprising the steps of:

- obtaining a ~~tissue replacement~~;
- soaking the ~~tissue replacement~~ for at least six hours in a solution comprising one or more sulfobetaines;
- ~~washing the tissue replacement in one or more solutions of a buffered salt;~~
- treating the ~~tissue replacement~~ in a mixture of one or more sulfobetaines with an anionic surface-active detergent; and
- washing the ~~tissue replacement~~ in one or more solutions of a buffered salt to remove the excess anionic surface-active detergent to form the native, acellular tissue replacement.

Claim 2 (Currently Amended) The method of claim 1, further comprising the step of storing the native, acellular tissue replacement in a buffered salt solution until needed.

Claim 3 (Original) The method of claim 1, wherein the sulfobetaines have hydrophilic tails of 10 to 16 carbons.

Claim 4 (Currently Amended) The method of claim 1, further comprising the step of:  
adhering one or more ~~components~~ bioactive agents to the ~~tissue replacement~~, ~~wherein the components are a bioactive agent.~~

Claim 5 (Withdrawn) The method of claim 4, wherein the cell is selected from the group consisting of bone, cartilage, dermal, muscular, thyroidal, parathyroidal, lymphoid, pancreatic, urinary, digestive, hepatic, biliary, vascular, nervous, reproductive and combinations thereof.

Claim 6 (Withdrawn) The method of claim 4, wherein the cells are obtained from a donor, a host, from cell culture from a donor or a host, or cell cultures of established cells, tissue cells, or transformed cell lines.

Claim 7 (Currently Amended) The method of claim 4, wherein the one or more bioactive compounds comprises a drug.

Claim 8 (Withdrawn) The method of claim 4, wherein the polymer is selected from the group consisting

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of naturally occurring, synthetically-derived, covalently crosslinkable, ionically crosslinkable, hydrophilic, and combinations thereof.

Claim 9 (Currently Amended) The method of claim 1, wherein the native, acellular tissue replacement comprises a structure selected from the group consisting of a suture, tube, sheet, film, scaffold, valve, limb replacement, tissue transplant, and joint for delivery into the body.

Claim 10 (Original) The method of claim 1, wherein the sulfobetaine comprises SB-16.

Claim 11 (Currently Amended) The method of claim 1, wherein the anionic surface-active detergent comprises Triton X-200.

Claim 12 (Currently Amended) The method of claim 1, wherein the step of washing the tissue replacement comprises one or more washes of in a buffered salt solution comprising 100 mM sodium and 50 mM phosphate for at least 15 minutes each.

Claim 13 (Currently Amended) The method of claim 1, wherein the tissue replacement is harvested from a mammalian cadaver.

Claim 14 (Currently Amended) The method of claim 13, wherein the tissue replacement is cleaned of fat and blood after harvesting and rinsed for two or more times three or more hours in deionized distilled water.

Claim 15 (Currently Amended) A native, acellular tissue replacement made by the method of claim 1.

Claim 16 (Currently Amended) A kit for tissue replacement comprising a ~~sterile~~ the native, acellular native tissue replacement of claim 15.

Claim 17 (Currently Amended) The kit of claim 16, wherein the native, acellular tissue replacement further comprises a suture, tube, sheet, film, scaffold, valve, limb replacement, tissue transplant or a joint.

Claim 18 (Currently Amended) The kit of claim 17, wherein the native, acellular tissue replacement further comprises ~~a cell~~, a polymer, a bioactive compound or combinations thereof.

Claim 19 (Currently Amended) The kit of claim 17, further comprising a sheet of instructions for use of the native, acellular tissue replacement.

Claim 20 (Withdrawn) A native tissue replacement obtained by the method comprising the steps of: a cell-free tissue obtained from an organ of a mammal made by a process comprising: soaking the replacement tissue in one or more sulfobetaine solutions for at least about 6 hours; washing the tissue replacement in one or more solutions of a buffered salt to remove excess detergent; extracting the replacement tissue in a mixture of one or more solutions of Triton X-200/SB-16 for at least about 6 hours;

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and washing the tissue replacement in one or more solutions of the buffered salt to remove excess Triton X-200/SB-16.

Claim 21 (withdrawn) The tissue replacement of claim 20, wherein the tissue is selected from the group consisting of bone, cartilage, dermal, muscular, thyroidal, parathyroidal, lymphoid, pancreatic, urinary, digestive, hepatic, biliary, vascular, nervous, reproductive and combinations thereof.

Claim 22 (withdrawn) The tissue replacement of claim 20, further comprising the step of adhering one or more components to the tissue replacement before storing.

Claim 23 (withdrawn) The tissue replacement of claim 22, further comprising a component selected from the group consisting of a cell, a polymer, a bioactive compound or combinations thereof.

Claim 24 (withdrawn) The tissue replacement of claim 20, further comprising one or more components adhered to the tissue replacement, wherein the components are selected from the group consisting of a cell, a polymer, a bioactive compound, and combinations thereof.

Claim 25 (withdrawn) The tissue replacement of claim 20, wherein the tissue replacement is stored at low temperatures until use.

Claim 26 (withdrawn) The tissue replacement of claim 20, wherein the tissue replacement is made by the method of claim 1.

Claim 27 (withdrawn) The tissue replacement of claim 20, wherein the tissue replacement is delivered to the body in the form of a structure selected from the group consisting of suture, tube, sheet, film, scaffold, valve, limb replacement, tissue transplant, and joint.

Claim 28 (withdrawn) The tissue replacement of claim 20, wherein the tissue replacement is further modified into a structure selected from the group consisting of suture, tube, sheet, film, scaffold, valve, and joint for delivery into the body.

Claim 29 (withdrawn) The tissue replacement of claim 20, further comprising one or more cells placed in the gap between prior to acellular graft implantation.

Claim 30 (withdrawn) The tissue replacement of claim 29, wherein the one or more cells comprise Schwann cells.

Claim 31 (withdrawn) An optimized acellular graft that supports axonal regeneration, guides the axons toward the distal nerve end and is immunologically tolerated.

Claim 32 (withdrawn) The acellular graft of claim 31, wherein the graft comprises a nerve graft.

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Claim 33 (withdrawn) The acellular graft of claim 31, further comprising the step of adhering one or more components to the graft before storing.

Claim 34 (withdrawn) The acellular graft of claim 31, further comprising a component selected from the group consisting of a cell, a polymer, a bioactive compound or combinations thereof.

Claim 35 (withdrawn) The acellular graft of claim 31, wherein the graft is stored at about 4 degrees centigrade in a sterile, buffered solution until use.

Claim 36 (withdrawn) The acellular graft of claim 31, wherein the graft is made by the method of claim 1.

Claim 37 (withdrawn) The acellular graft of claim 31, wherein the graft is delivered to the body in the form of a structure selected from the group consisting of suture, tube, sheet, film, scaffold, valve, limb replacement, tissue transplant, and joint.

Claim 38 (withdrawn) The acellular graft of claim 31, wherein the graft is further modified into a structure selected from the group consisting of suture, tube, sheet, film, scaffold, valve, and joint for delivery into the body.

Claim 39 (withdrawn) The acellular graft of claim 31, further comprising one or more cells placed in the gap between prior to graft implantation.

Claim 40 (withdrawn) The acellular graft of claim 31, wherein the graft causes a reduced T-cell mediated immune response.

**Please add new claims:**

41. (NEW) A method for preparing a native, acellular nerve tissue replacement comprising the steps of:
- obtaining a nerve tissue;
  - soaking the nerve tissue for at least six hours in a solution comprising one or more sulfobetaines;
  - treating the nerve tissue in a mixture of one or more sulfobetaines with an anionic surface-active detergent; and
  - washing the nerve tissue in one or more solutions of a buffered salt to remove the excess anionic surface-active detergent to form the native, acellular nerve tissue replacement, wherein the basal laminae and endoneurium layer retain their natural and generally original structure.
42. (NEW) A method for preparing a native, acellular tissue replacement comprising the steps of:

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obtaining a tissue;

soaking the tissue for at least six hours in a solution comprising one or more sulfobetaines;

treating the tissue in a mixture of one or more sulfobetaines with an anionic surface-active detergent; and

washing the tissue in one or more solutions of a buffered salt to remove the excess anionic surface-active detergent to form the native, acellular tissue replacement wherein the tissue replacement comprises a generally native structure and integrity.

43. (NEW) The method of claim 42, wherein the native, acellular tissue replacement, when implanted, has a T-cell mediated immune response that is less than an immune response triggered by an alloantigen implant.

44. (NEW) The method of claim 42, wherein the native acellular tissue replacement allows for higher axon density when implanted relative to a tissue graft made acellular by a freeze/thaw or a Triton X-100 process.